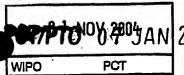
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## PATENT COOPERATION TREATY.

**PCT** 



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference P16552PC00				FOR FURTHER ACTION  See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No. PCT/SE 03/01195				International filing date 08.07.2003	e (day/mont	h/year)	Priority date (day/month/) 09.07.2002	/ear)
A6 <sup>-</sup>	International Patent Classification (IPC) or both national classification and IPC A61M39/10							
Applicant CARMEL PHARMA AB et al.								
1.	. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.							
2.	2. This REPORT consists of a total of 6 sheets, including this cover sheet.							
	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
	These annexes consist of a total of 2 sheets.							
3.	This	repor	t contains indications rela	ating to the following i	tems:			
	1	Ø	Basis of the opinion				•	
	11 111		Priority	aturta un control				
	The stability of opinion with regard to t			lovelty, inventive step and industrial applicability				
	<ul> <li>IV ☐ Lack of unity of invention</li> <li>V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> </ul>			applicability;				
	VI		Certain documents cited	1				
	VII		Certain defects in the in	• •				
	VIII   Certain observations on the international application							
Date of submission of the demand				Date of co	ompletion of this	report		
09.0	09.02.2004				29.10.2	004		
Name prelim	Name and mailing address of the International preliminary examining authority:				Authorize	d Officer		sinches Palenten.
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465			epmu d	Hedels,	B e No. +49 89 23	99-2329	The same of the sa	

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 03/01195

I.	<b>Basis</b>	of the	report
••	24313		I CDUIL

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	De	Description, Pages					
	1-7	•	as originally filed				
	Cla	ims, Numbers					
	1-1	0	filed with telefax on 11.10.2004				
	Dra	awings, Sheets					
		-4/4	as originally filed				
<ol> <li>With regard to the language, all the elements marked above were available or furnished to this A language in which the international application was filed, unless otherwise indicated under this ite</li> </ol>							
	The	ese elements were av	vailable or furnished to this Authority in the following language: , which is:				
		the language of a tr	he language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).				
		· · · · · · · · · · · · · · · · · · ·					
		the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).					
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:							
	☐ contained in the international application in written form.						
☐ filed together with the international application in computer readable form.			ne international application in computer readable form.				
<ul> <li>furnished subsequently to this Authority in written form.</li> <li>furnished subsequently to this Authority in computer readable form.</li> </ul>			ntly to this Authority in written form.				
			ntly to this Authority in computer readable form.				
The statement that the subsequently furnished written sequence listing does not go beyond the di in the international application as filed has been furnished.			the subsequently furnished written sequence listing does not go beyond the disclosure application as filed has been furnished.				
		The statement that the listing has been furn	the information recorded in computer readable form is identical to the written sequence ished.				
. The amendments have resulted in the cancellation of:							
		the description,	pages:				
		the claims,	Nos.:				
		the drawings,	sheets:				

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 03/01195

5.		This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).						
		(Any replacement sheet conta report.)	aining .	such amend	ments must be referred to under item 1 and annexed to this			
6.	Add	ditional observations, if necessary:						
Ш.	Nor	n-establishment of opinion w	/ith re	gard to nove	elty, inventive step and industrial applicability			
	The		d invei	ntion appears	s to be novel, to involve an inventive step (to be non-			
☐ the entire international application,								
⊠ claims Nos. 4-7								
because:  the said international application, or the said claims not require an international preliminary examination								
				the said clai ary examinat	ms Nos. relate to the following subject matter which does ion (specify):			
	×	the description, claims or drawings (indicate particular elements below) or said claims Nos. 4-7 are so unclear that no meaningful opinion could be formed (specify):						
see separate sheet								
the claims, or said claims Nos. are so inadequately supported by the description that no meaning could be formed.				ely supported by the description that no meaningful opinion				
		no international search report has been established for the said claims Nos.						
<ol><li>A meaningful international preliminary examination cannot be carried out due to the failure of the nucle or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrativ Instructions:</li></ol>					annot be carried out due to the failure of the nucleotide and/ ndard provided for in Annex C of the Administrative			
		the written form has not been furnished or does not comply with the Standard.						
		the computer readable form h	as not	been furnish	ned or does not comply with the Standard.			
٧.	Rea citat	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;						
1.	Stat	tement						
	Nov	elty (N)	Yes: No:	Claims Claims	1-3,8-10			
		ntive step (IS)	Yes: No:	Claims Claims	3 2,8-10			
		strial applicability (IA)	Yes: No:	Claims Claims	1-10			

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 03/01195

see separate sheet

#### Concerning section III.

Claims 4-7 do not meet the requirement of clarity (Art. 6 PCT). They relate to an injection component 11 which is not part of the invention according to claim 1. Thus they define the relationship to another device rather than specify the injection device of claim 1 per se (see the Guidelines for Examination, C-III, 4.8a).

#### Concerning section V.

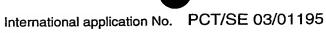
1. The injection device disclosed in US-A-5 158 554 (D2) (see Fig. 15) corresponds to the device depicted in Figs. 2 and 2a of the application and it comprises all the features of claim 1 with the exception of the first Luer fitting provided with a thread. As the lower end of the tubing 172 in Fig. 15 of D2 is not illustrated, it is clear that the above feature is not disclosed in D2.

Such Luer fittings were, however, not only common practice in this technical field but one of them is even illustrated in D2, Fig. 3.

It goes without saying that the skilled person would have provided such a generally known Luer fitting at the lower end of the device depicted in Fig. 15 if the lower end of the tubing 172 should be connected to a cannula inserted into a patient.

The arrangement of such a Luer fitting at the lower end of the tubing 172 is therefore on no rate regarded as involving an inventive step (Art. 33(3) PCT).

- 2. The features of the dependent claims 2 and 8-10 are also disclosed in D2 (see Fig. 15 and the corresponding description). Hence, these features also lack an inventive step.
- 3. The provision of a fourth path as defined in claim 3 is novel and cannot be derived in an obvious manner from the cited documents. Hence, this feature meets the requirements of Art. 33(2) and (3) PCT.
- 4. Claim 1 has not been properly delimited with respect to D2 as in Fig. 15 of D2, the first, second and third connecting components and the body are designed as an integrated unit in the same manner as depicted in Figs. 2 and 2a of the application (Rule 6.3 (b)).
- The description should have been brought into line with the new claims (Rule 5.1 5.



**EXAMINATION REPORT - SEPARATE SHEET** 

(a) (iii)).

D2 should in addition have been indicated in the description (Rule 5.1 (a) (ii)). 6.

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#### CLAIMS

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- 1. A device for injection, comprising a body (1) provided with a first channel (2) for conveyance of a first medical substance and a first connecting component (3) having a first port (4) for introduction of a first medical substance into said first channel (2), said connecting component (3) being connectable to an external unit, and a second channel (5) for conveyance of a second medical substance and a second connecting component (6) having a second port (7) which can be opened by means of an injection component for injecting a second medical substance into said second channel (5), and provided with a third connecting component (8) being common to the first and the second channels (2, 5) and having at least one third port (9) for conveying medical substances out from said first and second channels, c h a r a c t e r i z e d i n that said first (3), second (6) and third (8) connecting components and the body (1) are designed as an integrated unit, and said third connecting component (8) is a first luer fitting component provided with a thread (19) for releasable connection with a second luer fitting component having a corresponding thread, for creating a luer fitting coupling.
- 2. A device according to claim 1, characterized in that the body (1) has a channel portion (12) common to the first (2) and the second (5) channels, and said third port (9) constitutes an outlet for this channel portion (12) and thereby an outlet common to the first and the second channels.
- 3. A device according to claim 1, c h a r a c t e r i z e d i n that said third connecting component (8a) has a fourth port (23), wherein said third port (9a) constitutes an outlet for the first channel (2a) and said fourth port (23) constitutes an outlet for the second channel (5a).
- 4. A device according to any preceding claim, c h a r a c t e r i z e d in that said second port (7) has a first flexible membrane (17) for cooperation with a second flexible membrane arranged in an injection component (11) which is connectable to said second connecting component (6).
- 5. A device according to claim 4, c h a racterized in that the device has a means (18) for holding said second flexible membrane with a pressure against said first membrane (17).
- 6. A device according to claim 5, c h a r a c t e r i z e d i n that the pressure exceeds the yield point of the first and the second membranes.

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- A device according to claim 5 or 6, characterized in that the 7. pressure exceeds 150 kPa.
- A device according to any preceding claim, characterized in that the first luer fitting component comprises a male fitting (20) intended to cooperate with a corresponding female fitting of said second luer fitting component, which female fitting has a further channel, to form a connection sealed relative to the environment between the first (2) and the second (5) channels on one hand and said further channel on the other hand.
  - 9. A device according to claim 8, characterized in that the first luer fitting component comprises a ring (21) which is concentrically arranged relative to the male fitting (20) and at least partly encloses the male fitting (20), the ring being provided with said thread (19).
- 10. An injection arrangement comprising a device according to any of claims 1-9 for transmitting a first medical substance from an infusion bag (10) connected to said first connecting component (3) of the device, via the first channel (2), to a receiving unit connected to said third connecting component (8) of the device, and for transmitting a second medical substance from an injection component (11) connected to said second 20 connecting component (6) of the device, via the second channel (5), to said receiving unit.

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